

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 05 October 2001 (05.10.01)	
International application No. PCT/JP01/01204	Applicant's or agent's file reference PWO-20893
International filing date (day/month/year) 20 February 2001 (20.02.01)	Priority date (day/month/year) 21 February 2000 (21.02.00)
Applicant TODA, Ayako et al	

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

14 August 2001 (14.08.01)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Antonia MULLER Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY
PCT/JP01/01204 20 JAN 2002

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From the INTERNATIONAL BUREAU

**NOTICE INFORMING THE APPLICANT OF THE
COMMUNICATION OF THE INTERNATIONAL
APPLICATION TO THE DESIGNATED OFFICES**

(PCT Rule 47.1(c), first sentence)

To:

TABUSHI, Eiji
c/o Fujisawa Pharmaceutical Co.,
Ltd.
Osaka Factory
1-6, Kashima 2-chome
Yodogawa-ku, Osaka-shi
Osaka 532-8514
JAPON

Date of mailing (day/month/year) 23 August 2001 (23.08.01)		IMPORTANT NOTICE	
Applicant's or agent's file reference PWO-20893			
International application No. PCT/JP01/01204	International filing date (day/month/year) 20 February 2001 (20.02.01)	Priority date (day/month/year) 21 February 2000 (21.02.00)	
Applicant FUJISAWA PHARMACEUTICAL CO., LTD. et al			

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
KR,US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

AE,AG,AL,AM,AP,AT,AU,AZ,BA,BB,BG,BR,BY,BZ,CA,CH,CN,CR,CU,CZ,DE,DK,DM,DZ,EA,EE,EP,
ES,FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,
MK,MN,MW,MX,MZ,NO,NZ,OA,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,

The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on
23 August 2001 (23.08.01) under No. WO 01/60846

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Capibettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer J. Zahra Telephone No. (41-22) 338.83.38
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PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT/PCT RecPCT 30 JAN 2002

NOTIFICATION CONCERNING
SUBMISSION OR TRANSMITTAL
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

TABUSHI, Eiji
Fujisawa Pharmaceutical Co., Ltd.
Osaka Factory
1-6, Kashima 2-chome
Yodogawa-ku, Osaka-shi
Osaka 532-8514
JAPON

Date of mailing (day/month/year) 09 April 2001 (09.04.01)	
Applicant's or agent's file reference PWO-20893	IMPORTANT NOTIFICATION
International application No. PCT/JP01/01204	International filing date (day/month/year) 20 February 2001 (20.02.01)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 21 February 2000 (21.02.00)
Applicant FUJISAWA PHARMACEUTICAL CO., LTD. et al	

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
3. An asterisk(*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
4. The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
21 Febr 2000 (21.02.00)	PQ 5752	AU	30 Marc 2001 (30.03.01)
21 Augu 2000 (21.08.00)	PQ 9552	AU	30 Marc 2001 (30.03.01)
28 Dece 2000 (28.12.00)	PR 2344	AU	30 Marc 2001 (30.03.01)

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer Marc Salzman Telephone No. (41-22) 338.83.38
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Form PCT/IB/304 (July 1998)

003954456



PATENT COOPERATION TREATY

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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference PWO-20893	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/JP 01/ 01204	International filing date (day/month/year) 20/02/2001	(Earliest) Priority Date (day/month/year) 21/02/2000
Applicant FUJISAWA PHARMACEUTICAL CO., LTD. et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the title,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

CYCLIC HEXAPEPTIDE DERIVATIVES

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

Internal Application No.

A. CLASSIFICATION OF SUBJECT MATTER

According to International Patent Classification (IPC) or to both national classification and IPC

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

*& document member of the same patent family

Date of the actual completion of the international search

4 April 2001

Date of mailing of the international search report

10/04/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer _____

Deffner, C-A

INTERNATIONAL SEARCH REPORT

International Application No.
T/JP 01/01204

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>WO 99 40108 A (BARRETT DAVID ; MATSUDA KEIJI (JP); OHKI HIDENORI (JP); KAWABATA KO) 12 August 1999 (1999-08-12) cited in the application claim 1</p> <p>-----</p>	1-12

INTERNATIONAL SEARCH REPORT

tion on patent family members

Application No

T/JP 01/01204

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9611210 A	18-04-1996	AU 696949 B	24-09-1998
		AU 3578095 A	02-05-1996
		BR 9504791 A	22-10-1996
		CA 2202058 A	18-04-1996
		CN 1168675 A	24-12-1997
		EP 0788511 A	13-08-1997
		FI 971397 A	27-05-1997
		HU 77736 A	28-07-1998
		JP 10324695 A	08-12-1998
		JP 2897427 B	31-05-1999
		JP 10507174 T	14-07-1998
		NO 971544 A	04-06-1997
		TR 960461 A	21-07-1996
		US 6107458 A	22-08-2000
		ZA 9508458 A	07-05-1996
WO 9425048 A	10-11-1994	AU 677656 B	01-05-1997
		AU 6632794 A	21-11-1994
		CA 2159835 A	10-11-1994
		EP 0707488 A	24-04-1996
		JP 8509722 T	15-10-1996
EP 0535959 A	07-04-1993	US 5939384 A	17-08-1999
		AT 147757 T	15-02-1997
		CA 2079171 A	02-04-1993
		DE 69216746 D	27-02-1997
		DE 69216746 T	03-07-1997
		DK 535959 T	09-06-1997
		ES 2098455 T	01-05-1997
		GR 3022292 T	30-04-1997
		JP 2096302 C	02-10-1996
		JP 6234795 A	23-08-1994
		JP 7121958 B	25-12-1995
WO 9940108 A	12-08-1999	AU 2299899 A	23-08-1999
		BR 9907967 A	17-10-2000
		EP 1053247 A	22-11-2000
		NO 20003996 A	09-10-2000

PATENT COOPERATION TREATY

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REC'D 15 FEB 2002

WIPO

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

10/030161

Applicant's or agent's file reference PWO-20893	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP01/01204	International filing date (day/month/year) 20/02/2001	Priority date (day/month/year) 21/02/2000
International Patent Classification (IPC) or national classification and IPC C07K7/56		
Applicant FUJISAWA PHARMACEUTICAL CO., LTD. et al.		

RECEIVED
OCT 25 2002
TECH CENTER 1600/2900

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 14/08/2001	Date of completion of this report 13.02.2002
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Deffner, C-A Telephone No. +49 89 2399 8535



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP01/01204

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-191 as originally filed

Claims, No.:

1-12 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/JP01/01204

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes:	Claims	1-12
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-12
Industrial applicability (IA)	Yes:	Claims	1-9,11,12
	No:	Claims	10

**2. Citations and explanations
see separate sheet**

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/JP01/01204

Reference is made to the following document/s/:

D1: WO-A-96112110

D2: WO-A-9425048

D3: EP-A-535959

D4: WO-A-9940108

- 1). The terms 'lower' and 'higher' and 'substituted with suitable substituents' are vague and have no defined technical meaning. Therefore the requirements of Article 6 PCT are not met.
- 2). For the assessment of the present claim 10 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.
- 3). With respect to the cited prior art present compounds appear to be novel (Article 33(2) PCT).
- 4). The essential difference between present compounds and those disclosed in (D1) to (D4) is the substituent R^3 of present formula I being lower alkyl substituted with one or more hydroxy or protected hydroxy groups. All other substituents are disclosed in (D1) to (D4).

With respect to this the problem to be solved can be defined as the provision of further cyclic hexapeptides with antibiotic activity.

Propanolamine derivatives are disclosed in (D2) and (D3) showing that a variety of different substituents are possible in position R^3 of formula 1.

Therefore it appears that the skilled person looking for further antibiotic compounds could have expected that the relative small modification introduced in the hexapeptides of (D1) and (D4) would lead to compounds having essentially the same activity. Therefore present subject-matter appears not to involve an inventive step (Article 33(3) PCT).

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/JP01/01204

- 5). Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents (D2) and (D3) is not mentioned in the description, nor are these documents identified therein.